REMARKS

Claims 1, 2, 8, 9, 15-17, and 19-24 are pending in the application. Claims 5, 12, and 18 have been canceled without prejudice. Applicant reserves the right to file a continuing application drawn to the subject matter of these canceled claims. New claims 19-24 have been added herein. Support for claim 19 is found at page 27, lines 6-9. Support for claim 20 is found at page 26, lines 25-35, and page 27, lines 6-9. Support for claim 21 is found at page 26, lines 28-35. Support for claims 22-24 is found at page 27, lines 9-16. No new matter has been added to the application by virtue of these amendments.

The application now contains 14 total claims and 8 independent claims. Applicant previously paid application fees for 14 independent claims. Thus, no additional excess claims fees are due. Notwithstanding, the Commissioner is hereby authorized to charge any deficiency in fees or credit any overpayment in connection with this paper to Deposit Account No. 50-0836.

I. Claim Objection

Claim 15 was objected to for an informality in spelling. Claim 15 has been amended to correct a typographical error.

Withdrawal of the objection to this claim is respectfully requested.

II. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-2, 5, 8-9, 12, and 15-18 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Applicable standards for making a determination under 35 U.S.C. § 112, second paragraph, have been reviewed previously. Such review is hereby incorporated by reference.

With that background in mind, the rejection of claims under 35 U.S.C. § 112, second paragraph, will now be discussed.

Claims 1, 15, and 16 were rejected for reciting "duplicate genes . . . isolated from each other on opposite homeologous genomes." These claims have been amended wherein these terms have been removed. Therefore, Applicant respectfully submits that this rejection is obviated.

Claims 1, 2, 5, and 15-17 were rejected for allegedly being incomplete for omitting essential steps. The Examiner alleged that "the omitted steps are those involved in producing a polyploid derivative line. What does one have to do to produce such lines?" In this connection, MPEP § 2172.01 states (emphasis added):

> A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. . . . Such essential matter may include missing elements, steps or

> necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.
>
> In addition, a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention.

Applicant respectfully submits that essential elements of the application as defined in the specification have not been omitted. Applicant also respectfully submits that numerous decisions by the Federal Circuit and the CCPA state that, because the specification is directed to those having ordinary skill in the relevant art, it is not necessary to disclose that which is already known in the art. E.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986) ([A] patent need not teach, and preferably omits, what is well known in the art."), In re Howarth, 210 U.S.P.Q. 689, 691-92 (C.C.P.A 1981). Thus, it is not necessary for a patent, in either the specification or the claims, to teach what is well known in the art. In fact, a patent preferably omits such well known subject matter. Applicant respectfully submits that making polyploids is well known in the art, thus it is not required to disclose or claim such well known subject matter.

For example, if the claim at issue were a method of making a cake, and this hypothetical claim contained a step of "mixing flour, sugar, and water," a rejection could be lodged that steps

were omitted in not specifying where the flour is obtained. If the claim were then amended to specify that the flour was obtained by grinding wheat, then another rejection could be lodged for omitting the essential steps of specifying where the wheat was obtained. If the claim were then amended to specify that the wheat was obtained by planting wheat seeds, growing wheat plants from the wheat seeds, and harvesting wheat kernels from the wheat plants, then another rejection for omitting essential steps could be lodged for not specifying how the wheat plants were watered, fertilized, and so forth. In this hypothetical case, a person skilled in the art of making cakes knows where flour comes from and how to obtain it, and for this reason is it not necessary to describe in the specification or include in the claim more details concerning where the flour comes from or how it is obtained.

Similarly, Applicant respectfully submits that it is well known in the art how to make polyploids. Making polyploids is one of the basic skills that persons skilled in the art of plant breeding know how to do without being further instructed in the patent claims. Further, Applicant has not omitted steps that were disclosed in the specification as being essential. Applicant disclosed in the specification that it was essential to make polyploids, and that has been claimed. Because methods of making polyploids are well known in the art, Applicant mentioned several

illustrative methods that can be used for making polyploids, including treatment with spindle inhibitors such as colchicine (page 26, lines 25-28; page 27, lines 6-9), $B_{...}$ hybridization, and tissue culture (page 26, lines 28-35). Thus, a person skilled in the art would know the metes and bounds of what is claimed without the need to include in the claim what are merely standard methods of making polyploids. For these reasons, it is respectfully submitted that the rejection of claims 1, 2, and 15-17 as lacking essential steps is not well founded and should be withdrawn.

Claim 2 was rejected for allegedly lacking antecedent basis for the term "said apomictic polyploid derivative line exhibiting segmental allopolyploidy." Claim 2 has been amended and no longer contains such terminology, thus Applicant respectfully submits that the rejection is obviated.

Claim 2 was rejected for allegedly lacking clarity with respect to part (b) in reciting "selfing or hybridizing with a similar plant." The Examiner stated that it is unclear how one can self with a similar plant when selfing involves crossing with the plant itself. Applicant believes that the Examiner has answered the question. Selfing is crossing with the plant itself, while hybridizing with a similar plant means crossing with a different plant. A person skilled in the art would understand the differences between selfing and hybridizing with another plant,

thus the metes and bounds of this limitation are not indefinite. The Examiner further inquired whether selfing or crossing with a similar plant is all that is required to obtain unreduced egg fertility or parthenogenesis. The unreduced egg fertility or parthenogenesis comes from the apomictic starting material. The increased fertility comes from the selfing or hybridizing to a similar plant. Hybrids often exhibit outcrossing depression and low fertility. As plants are bred through additional generations, individuals with much greater fertility can routinely be selected.

Claims 5 and 18 were rejected as allegedly being incomplete for omitting essential steps involved in producing an apomictic plant and genetically stabilizing it, for reciting "genetically divergent," and for allegedly being unclear concerning what the plant is crossed to, for how many generations, and what other steps are involved in breeding the plant. Claims 5 and 18 have been canceled, thus such rejections are moot.

Claims 15-16 were rejected for allegedly being incomplete for omitting essential steps. The Examiner again enquired what one has to do to produce segmental allopolyploids. The steps for making polyploids are well known in the art, as described above. It is well known in the art that allopolyploids are formed by interspecific crosses, while autopolyploids are formed by intraspecific crosses. For these reasons, it is respectfully

submitted that it is not necessary under the applicable patent laws, rules, or regulations to include the substeps that would be needed to make segmental allopolyploids. The step of making segmental allopolyploids has been set out in the claim, and it is not necessary or desirable to include substeps when such substeps are well known in the art.

Claim 17 was rejected for allegedly failing to provide antecedent basis for "said plant" in part (b). The antecedent basis for "said plant" is in the preamble of claim 17, thus withdrawal of this rejection is respectfully requested.

Claim 17 was also rejected for allegedly being unclear concerning "which plant the plant is crossed to, or for how may generations, or what any of the other steps are in 'breeding' the plant." Claim 17 has been amended wherein the "breeding" terminology has been replaced with steps that result in the claimed product.

Claims 18 was rejected for allegedly lacking antecedent basis for "said . . . near obligate derivative line." Claim 18 has been canceled, thus this rejection is moot.

In view of the explanations, arguments, and amendments presented herein, it is respectfully submitted that all pending claims are in compliance with the requirements of Section 112, second paragraph.

III. Enablement Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-2, 5, 8-9, 12, and 15-18 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). See also, *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). However, a patent need not teach, and preferably omits, what is well known in the art. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986). Determining enablement is a question of law based on underlying factual findings. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Menours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue if such experimentation is typical in the art. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221

USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia* , 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985); *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

There are many factors to be considered when making a determination whether or not a disclosure satisfies the enablement requirement and whether or not any necessary experimentation is undue, among which are: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill in the art; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence or absence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement).

It is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while

ignoring one or more of the others. MPEP § 2164.01(a). The analysis must consider all of the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. 858 F.2d at 737, 740, 8 USPQ2d at 1404, 1407.

A. Breadth of the Claims

This invention relates to methods for stabilizing and controlling apomixis. Stabilizing apomixis refers to manipulating apomictic plants such that sexually derived progeny, which are occasionally produced facultatively from apomictic plants, tend to be apomictic like the mother plant, though otherwise genetically recombined, instead of being sexual revertants. Page 1, lines 5-11. Stated another way, producing a genetically stabilized facultative apomictic mother plant means assuring that the average frequency of sexual seed formation among sexually derived progeny of the produced facultative apomictic mother plant does not exceed that of such mother plant. Page 12, lines 10-13. Controlling apomixis refers to processes that modify in an apomict the frequency in which seed are produced sexually as opposed to asexually (apomictically). Preventing sexual seed formation completely, i.e. converting a facultative apomict to an obligate apomict, is a form of control that also represents a unique form of genetic stabilization in that an obligate apomict cannot produce

progeny sexually and hence cannot produce sexual segregants. Hence, conferring obligate apomixis (elimination of sexual seed formation) is a special form of genetic stabilization that can be used when interspecific hybridization is not desirable. Page 8, lines 3-7. Controlling apomixis also includes conferring obligate apomixis except when the plant is induced to be facultatively apomictic, or permitting facultative apomixis to occur except when the plant is induced to be obligately apomictic. Page 1, lines 11-16. The technologies described herein to accomplish stabilization and control are pioneering technologies, and, as such, these technologies are broadly claimed.

It has been consistently held that merely pointing out breadth in claim terminology is not sufficient to sustain an allegation of lack of enablement and that a party asserting lack of compliance with 35 U.S.C. § 112, first paragraph, has the burden of presenting cogent technical reasoning or objective evidence to support its position regarding enablement. *Horton v. Stevens*, 7 USPQ 1245 (Bd. App. & Int. 1988).

Moreover, claims of various scopes are present in the application. Applicant is seeking broad patent protection on the presently claimed invention. However, claims of narrow and intermediate scope are also present in the application. The disclosure enables a person skilled in the art to make and use the

claimed invention of narrow, intermediate, and broad scope. If a person skilled in the art follows the steps set out in the claims, genetically stabilized apomictic plants will be produced.

B. Nature of the Invention

This application relates to stabilizing and controlling apomixis. Stabilizing apomixis means assuring that the average frequency of sexual seed formation among sexually derived progeny of an apomictic mother plant does not exceed that of such apomictic mother plant, and it includes the special case in which a facultative apomict is converted to an obligate apomict, which does not (or only rarely) reproduce sexually. Page 12, lines 10-13; page 1, lines 5-11; page 8, lines 3-7. Controlling apomixis refers to assuring that apomicts express obligate apomixis, or obligate apomixis except when induced to be facultatively apomictic, or facultative apomixis except when induced to be obligately apomictic. Page 1, lines 11-16. The elected claims relate to genetically stabilizing an apomictic plant exhibiting genetic instability for apomixis by producing a polyploid derivative line thereof. In the polyploid line, sexual segregation is suppressed, which results in stabilization of apomixis because the genes responsible for apomixis are do not readily segregate. The elected claims also relate to the special case of stabilization

in which control of apomixis is exercised to produce an obligate apomict in which recombination is completely suppressed. In such cases, homeology is not required to achieve genetic stabilization, because sexual seed formation, with its inherent risk of segregation back to sexuality, is no longer an issue. Plant breeding is a well known technology, and techniques used in the art of plant breeding, such as bagging or emasculation of female parents, pollination, identification and selection of apomictic hybrids, chromosome doubling, B_{III} hybridization, and the like, are routine and have been used for many years.

Prior to the pioneering discoveries of the inventor described in the present application and in co-pending U.S. Patent Application No. 09/576,623 for Methods for Producing Apomictic Plants, it was not known in the art how to select sexual parent plants and hybridize them such that apomictic progeny could be selected. An extension or improvement of such methods for producing apomictic plants is the presently claimed invention relating to methods for stabilizing and controlling apomixis. Once the inventor understood the genetic processes that lead to expression of apomixis, it was then possible for the inventor to devise methods for stabilizing and controlling apomixis using well known, traditional plant breeding methods.

Therefore, th factor of the nature of the invention weighs in favor of the present disclosure being an enabling disclosure.

C. State of the Prior Art

Conventional wisdom prior to the filing of the instant specification held that apomixis is caused by an apomixis gene (or two) that is simply inherited. This conventional paradigm is clearly challenged in co-pending U.S. Patent Application No. 09/576,623 and the present application.

The state of the prior art is to attempt to transfer the supposed one or two apomixis genes into sexual plant lines by breeding such lines with apomictic wild relative plants, which are usually used as the pollen (or sperm) donors because eggs of an apomict usually originate asexually and produce asexual (clonal) seed, i.e. without union of egg and sperm nuclei. The present application repudiates the apomixis gene theory and is based on asynchronous expression of many duplicate genes required for female or seed development. Plant breeding is well known in the art. Any skilled plant breeder would be able to stabilize apomixis in a plant line exhibiting genetic instability for apomixis by following the guidelines set out in the present application.

Therefore, this factor of the state of the prior art weighs in favor of the present application containing an enabling disclosure.

D. Level of One of Ordinary Skill in the Art

The level of skill of a person of ordinary skill in the art is relatively high. A person of ordinary skill in the art as of the filing date of the invention would know how to select plants for a plant breeding experiment and hybridize the selected plant lines by plant breeding. Such person would know how to recover seed from the hybridization, sow such seed, raise plants from such seed, and select hybrid lines from among the progeny. Such person would know how to recognize apomixis in plants and how to determine whether the apomixis trait is unstable (as defined in the present disclosure) or not. Such person would know how to make polyploid derivative lines by chromosome doubling and $B_{I::}$ hybridization.

Thus, this factor of the level of one of ordinary skill in the art weighs in favor of the present disclosure being an enabling disclosure.

E. Level of Predictability of the Art

The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art, as well as the predictability of the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). In other words, the more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the

more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention to be enabling. MPEP § 2164.03. Further,

> [t]he "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. . . . The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required.

MPEP § 2164.03.

The Examiner alleged that this art is so unpredictable that an enabling disclosure has not been provided for the presently claimed invention. The Examiner stated that the instant specification only provides guidance for identification of *Antennaria*, *Tripsacum*, and *Sorghum* as plants that meet the criteria of the specification. This is incorrect. First, it should be recognized that *Antennaria* is a dicot, and *Tripsacum* and *Sorghum* are monocots. Thus, Applicant has provided guidance as to how to make and use the

invention using examples of both major types of angiospermous plants. Second, plant breeding is well known for both monocots and dicots. It is predictable for a person skilled in the art of plant breeding to be able to identify apomixis by progeny testing, to identify when apomixis is genetically unstable (i.e., when sexually produced progeny exhibit lower percentages of apomixis than the parent plant), double chromosome numbers or otherwise produce polyploid plants, to identify meiotic mutants and cross them with selected plants, and the like. Therefore, one skilled in the art can extrapolate the results that will be obtained when using a dicot other than *Antennaria* or monocots other than *Tripsacum* or *Sorghum*. One skilled in the art can readily anticipate what will be obtained by selecting plants other than *Antennaria*, *Tripsacum*, or *Sorghum* because breeding methods are so well known for both monocots and dicots.

The Examiner further stated that the "specification fails to provide guidance for methods of determining if duplicate genes responsible for apomixis are isolated from each other or are on opposite homologous chromosomes, or for suppression of recombination among homeologous genomes." The claims do not include a step of determining where the apomixis genes occur in the genome. The claims relate to determining whether apomixis is unstable and, if so, then stabilizing apomixis by amphiploidization

or introgression of a female meiotic mutation. The result of amphiploidization is suppression of segregation of the genes responsible for apomixis. The suppression of segregation by amphiploidization can be illustrated by a simple model. If, for the sake of example, apomixis in a diploid plant were a single-gene trait, and it was essential that the plant be heterozygous at the hypothetical apomixis gene for apomixis to be expressed, then an apomictic plant might be described as having a genotype of Aa. Selfing of this hypothetical apomictic plant would result in progeny in which half the progeny would be homozygous (AA or aa) and sexual, and the other half of the progeny would be heterozygous and apomictic. If the plant were tetraploid, however, and had an AaAa genotype, selfing of this apomictic tetraploid would result in complete homozygosity in only one-eighth of the progeny (AAAA or aaaa). Thus, the tetraploid is genetically stabilized for apomixis because complete homozygosity occurs less frequently than in the diploid. It is not necessary to know how many apomixis genes there are or where they are located in the genome. Doubling the chromosome number of the unstable apomict results in genetic stabilization of apomixis because genetic segregation is suppressed.

Therefore, the predictability of this invention is much greater than has been recognized by the Examiner. It requires

routine procedures for a person skilled in the art of plant breeding to produce a genetically stable polyploid apomictic hybrid from a genetically unstable apomictic diploid hybrid or to confer sexual sterility in a genetically unstable apomict by conferring sexual sterility, through odd polyploidy or through meiotic mutants, while keeping apomictic fertility intact.

F. Amount of Direction Provided by the Inventor

The application contains a thorough explanation of how the present duplicate-gene asynchrony approach to making apomictic plants is consistent with the observations that have been made in the apomixis field over many years and further explains why the theories and assumptions of the prior art are deficient. Once it is understood by a person skilled in the art of plant breeding how apomixis arises, it is a routine matter to (a) produce polyploids by chromosome doubling or $B_{...}$ hybridization such that genetic segregation is suppressed or (b) to confer sexual sterility in a genetically unstable apomict as discussed above.

G. Working Examples

Compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, does not turn on whether a working example is disclosed. MPEP § 2164.02. The presence or absence of working

examples, however, is a factor to be considered. Nevertheless, a working example of producing a genetically stable apomict from a facultatively apomictic line, *Tripsacum* hybrid (*T. laxum* x *T. pilosum* amphiploid), has been provided in the current specification, page 33, lines 1-7. In this example, a tetraploid facultative apomict (approx. 50% diplosporous embryo sac formation) was converted to a near obligate genetically-stabilized apomict by producing a triploid (odd ploidy level) derivative line. The triploid derivative was apomictically fertile (80% apomictic embryo sacs) but sexually sterile (20% abortive sexual meioses or sexual embryo sacs). Since this plant fails to produce seed sexually (sexual seed abortion conferred through odd ploidy), it is genetically stable. Page 8, lines 3-7; page 10, line 34, to page 11, line 1.

H. Quantity of Experimentation

Some experimentation will likely be necessary with each new species or genus of plant used in making apomictic hybrids. However, based on the guidance provided in the specification, such experimentation would be merely routine.

Based on all of these factors, the great preponderance of the evidence weighs in favor of an enabling disclosure having been provided. For these reasons, it is respectfully submitted that the requirements of an enabling disclosure under 35 U.S.C. § 112, first paragraph, have been met. Thus, withdrawal of the rejection on this ground is respectfully requested.

IV. Written Description Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1, 2, 5, 8-9, 12, and 15-18 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking a written description of the invention.

The written description requirement of § 112, first paragraph was reviewed and summarized by the Federal Circuit in *Vas-Cath Inv. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1117, 1119 (Fed. Cir. 1991) (emphasis in original) as follows:

> [W]e hereby reaffirm . . . that 35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader that to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession <u>of the invention</u>. The invention is, for purposes of the "written description" inquiry, <u>whatever is now claimed</u>. . . . [T]he proper test is whether the [written description] conveyed with reasonable clarity to those of ordinary skill that [the applicant] had in fact invented the [invention] recited in those claims.

The test, then, is whether the written description conveyed with reasonable clarity to those of ordinary skill that Applicant had in fact invented the method of producing stable apomicts from unstable apomicts as recited in the claims. The written description makes reasonably clear chromosome numbers of unstable apomicts are doubled, such as through treatment with spindle inhibitors, tissue culture, $B_{...}$ hybridization, and the like. The written description also makes reasonably clear how the sexual sterility can be obtained, such as through making of polyploids with odd ploidy levels or introgressing meiotic mutations. The written description makes reasonable clear that an working example of the invention was described. The written description makes reasonably clear that standard methods of plant breeding in monocots and dicots are used to double the chromosome numbers or otherwise manipulate ploidy levels. It is believed and thus urged that the written description conveys with reasonable clarity to a person of ordinary skill in the art that a method of producing genetically stabilized apomictic polyploids has been invented as claimed.

Therefore, it is respectfully submitted that the application is in compliance with the written description requirement of Section 112, first paragraph, and withdrawal of this rejection is respectfully requested.

V. Rejections under 35 U.S.C. § 102

Before discussing rejections based upon 35 U.S.C. § 102, it is proper to state that to sustain a rejection under § 102 the Patent and Trademark Office must abide by the following statement of the law.

> Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In addition, the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964).

Akzo N.V. v. U.S. Int'l Trade Comm'n, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986).

The Examiner rejected claims 1-2, 5, 8-9, 12, and 15-18 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,811,636 (hereinafter, "Hanna '636).

Hannah '636 discloses at column 4 line 45 through column 5 line 33 that interspecific hybrids of sexual pearl millet with wild relatives are generally highly male sterile, but progress in trying to introgress apomixis genes into pearl millet requires some normal male meiosis. This is achieved by elevating male fertility in complex hybrids produced between induced tetraploid pearl millet, the wild apomictic species *Pennisetum squamulatum*, and a third species, *P. purpureum*. Hannah '636 fails to disclose doubling the

chromosome number of apomictic plants that are genetically unstable for apomixis, thereby resulting in apomictic plants that are genetically stable for apomixis. Hannah '636 fails to disclose that the apomictic plant is genetically unstable, much less stabilizing such apomictic plant. Instead, Hannah '636 discloses increasing the male fertility of hybrids between sexual pearl millet and an apomictic wild relative. Therefore, Hannah '636 fails to disclose each and every element of the claimed invention, and thus fails to anticipate the presently claimed invention.

Hannah '636 fails to disclose any method for genetically stabilizing an apomictic plant exhibiting genetic instability, as the terms "stabilizing" and "genetic instability" are used in the present application. Hannah '636 treats the subject of male fertility, but fails to disclose anything about the average frequency of apomixis from generation to generation. Therefore, Hannah '636 fails to disclose each and every element of the presently claimed invention, and thus fails to anticipate the claims at issue.

The Examiner alleged that "Table 1 shows the production of progeny that are only apomictic." This is incorrect. Table 1 shows a pedigree for the transfer of the genetic mechanism controlling apomixis in Pennisetum to pearl millet. The progeny are sexually crossed with a sexual recurrent parent. If the

progeny were "only apomictic," how are the crosses made? Table 1 states nothing about the stability or instability of apomixis in the various hybrids, thus it fails to anticipate the presently claimed invention. Table 2 was also referred to by the Examiner. Table 2 also fails to disclose the stability or instability of apomixis in the various hybrids. The Examiner noted that the claims do not recite any steps for determining if an apomictic plant is genetically stabilized. This is because such a step is not necessary for genetically stabilizing an apomictic plant. If the apomictic plant is genetically stabilized, then it is genetically stabilized whether or not somebody determines that it is genetically stabilized.

Hannah '636 fails to disclose each and every limitation of the presently claimed invention, thus it fails to anticipate the invention. Withdrawal of the rejection is respectfully requested.

Claims 1-2, 8-9, and 15-16 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Ellerström (1977).

S. Ellerström, 87 Hereditas 107-120 (1977) (hereinafter, "Ellerström (1977)"), reported a high level of sterility in amphidiploid hybrid *Raphanobrassica* from crosses between fodder radish and marrow-stem kale. On average, only 0.2 hybrid seeds were obtained per pollinated flower. Seed set in the first generation hybrids was only 0.1 seeds per pollinated flower.

However, repeated selection during 6 generations improved seed fertility to 2.3 seeds per pollinated flower.

Ellerström (1977) failed to disclose doubling the chromosome number of genetically unstable apomicts to results in genetically stable apomicts. Ellerström (1977) treats the subject of sterility and improving seed set through selection over 6 generations, but fails to disclose anything about the average frequency of apomixis from generation to generation, and thus did not disclose whether or not the apomicts were genetically stable or unstable. Therefore, Ellerström (1977) fails to disclose each and every element of the presently claimed invention, and thus fails to anticipate the claims at issue.

Claims 1, 8, and 15-16 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by S. Saran et al., 11 J. Cytol. Genet. 22-28 (1976) (hereinafter, "Saran").

Saran describes the effects of different photoperiods on facultativeness of a facultatively apomictic tetraploid *Dichanthium intermedium* hybrid whose parents were also members of the facultatively-apomictic species *D. intermedium* (page 22, first sentence, Materials and Methods). The last sentence of the introduction (page 22) implicitly states what the paper deals with, i.e. "the effect of photoperiod on the mode of reproduction in the facultatively apomictic compilospecies, *Dichanthium intermedium*."

More succinctly, Saran describes apomictic hybrids produced from apomictic parents. Neither this paper nor subsequent review articles and books on apomixis that review this paper (e.g., S.E. Asker & L. Jerling, Apomixis in Plants 90 (CRC Press 1992); M. Mogie, *The Evolution of Asexual Reproduction in Plants* 150 (Chapman and Hall, London 1992), disclose or suggest that Saran produced (or claimed to have produced) an apomictic *Dichanthium* by hybridizing two sexual *Dichanthium* genotypes (absence of facultative expression of apomixis).

The Examiner stated that Saran teaches crossing two biotypes of *D. intermedium* to produce a tetraploid plant and that this plant had genetically stabilized apomixis. Saran states that *D. intermedium* is a facultatively apomictic compilospecies (bottom of Introduction at page 22). Saran is silent as to whether or not *D. intermedium* is genetically stable or genetically unstable for apomixis. Saran teaches that a tetraploid hybrid was produced by crossing two biotypes of *D. intermedium*. Saran does not state the ploidy level of the two parent plants that were crossed to make the tetraploid hybrid. Therefore, Saran fails to teach doubling the chromosome number. Moreover, neither Table 1 nor Fig. 1 states anything about the genetic stability or genetic instability of the hybrid for apomixis. Table 1 and Fig. 1 merely present the number and percentage of sexual and apomictic embryo sacs in the hybrids.

Therefore, Saran fails to disclose each and every element of the presently claimed invention and, thus, fails to anticipate the claims. Withdrawal of the rejection of claims 5 and 12 under 35 U.S.C. § 102(b) is respectfully requested.

Claims 8-9 and 12 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,710,367 (hereinafter, "Kindiger"). Alternatively, these claims were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Kindiger. The rejection under section 102(e) will be dealt with in this section, while the rejection under section 103 will be dealt with in the section that follows. Claim 12 has been canceled, therefore the rejection of that claim is moot.

Kindiger discloses apomictic maize/*Tripsacum* hybrids having a ratio of maize to *Tripsacum* chromosomes of at least 30:9. At column 6, Kindiger discusses a model for inheritance of apomixis and expected maternal fertility. Kindiger fails to disclose instability of apomixis as the terms "stability" and "instability" are used in the present application, and further fails to disclose any method for stabilizing apomixis from generation to generation in apomictic lines exhibiting instability for the apomixis trait.

At column 15, Kindiger describes making an F1 hybrid (H278) from a cross between a tetraploid maize (V182) and a tetraploid *Tripsacum dactyloides* accession. Kindiger does not disclose

whether or not the H278 hybrid was genetically stable or genetically unstable for apomixis and did not double the chromosome number thereof.

Kindiger, therefore, fails to disclose each and every element of the presently claimed invention. Thus, Kindiger fails to anticipate the claims at issue. For these reasons, withdrawal of the rejection of claims 8 and 9 under 35 U.S.C. § 102(e) over Kindiger is respectfully requested.

In view of the above, none of the claims presently under consideration is anticipated by any of the cited references. Withdrawal of all rejections under Section 102 is respectfully requested.

VI. Rejections Under 35 U.S.C. § 103

Before responding directly to the issues raised by the Examiner under Section 103, the legal foundation for sustaining such a rejection will be reviewed. Briefly, the burden is first on the Patent Office to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). If no *prima facie* case of obviousness is established, then a rejection under Section 103 cannot properly be sustained. *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). If the Patent Office

establishes a *prima facie* case of obviousness, then the burden of production shifts to the applicant to provide appropriate rebuttal, but the burden of persuasion always remains with the Patent Office. *Id.* Such rebuttal may include arguments, amendments, and/or presentation of objective indicia of nonobviousness. Evidence of these objective indicia are always relevant to a determination of nonobviousness whether or not a *prima facie* case of obviousness has been established. *Stratoflex Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871, 879 (Fed. Cir. 1987). To establish a *prima facie* case of obviousness, the Examiner must show all of the limitations of the claimed invention in the prior art. *In re Ehrreich*, 200 U.S.P.Q. 504, 509-11 (C.C.P.A. 1979). The subject matter of the invention must be considered as a whole and through the eyes of a hypothetical person of ordinary skill, not expert skill, in the relevant art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983). References must also be considered as a whole, including subject matter that teaches away from the invention as well as subject matter that suggests the invention, and not for their isolated teachings. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985). References may be combined if there is a suggestion, motivation, or incentive in the prior art to make such a combination. *In re Dillon*, 16 U.S.P.Q.2d 1897, 1901

(Fed. Cir. 1990) (en banc); *In re Jones*, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992). It is not permissible to use hindsight to pick and choose among isolated teachings in the art after first having read Applicant's application to learn the pattern of the invention. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

Pursuant to established legal authority, patentability under 35 U.S.C. § 103 requires a four-step analysis, which involves determining (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed inventions, (3) the level of skill in the art, and (4) the objective evidence of nonobviousness that may have been presented. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 311, 314 (Fed. Cir. 1983). After all of these factors have been considered, the ultimate legal conclusion on the issue of obviousness must be reached. With the above background in mind the rejections under 35 U.S.C. § 103 will be discussed.

Claims 8-9 and 12 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Kindiger. Claim 12 has been canceled, thus this rejection is moot as to that claim. The teachings of Kindiger were briefly reviewed in the preceding section relating to Section 102. Kindiger fails to disclose instability of apomixis as the terms "stability" and "instability" are used in the present

application, and further fails to disclose or suggest any method for stabilizing apomixis from generation to generation in apomictic lines exhibiting instability for the apomixis trait. Kindiger fails to disclose doubling the chromosome number of a genetically unstable apomict to produce a genetically stable apomict.

Kindiger, therefore, fails to show all the limitations of the presently claimed invention in the prior art. Thus, Kindiger fails to render the presently claimed invention obvious to a person of ordinary skill in the art at the time the invention was made. For this reason, a *prima facie* case of obviousness has not been established. Withdrawal of this ground of rejection is thus respectfully requested.

Claims 1-2, 5, 8-9, 12, and 15-18 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Ellerström (1977) in view of Ellerström (1983). This rejection is moot as to claims 5 and 12 because they have been canceled. Both Ellerström (1977) and Ellerström (1983) were discussed above. Neither Ellerström (1977) nor Ellerström (1983), alone or in combination, discloses or suggests genetic instability of the apomixis trait, much less a method of stabilizing such genetic instability. Therefore, the combination of Ellerström (1977) and Ellerström (1983) fails to show all the limitations of the presently claimed invention. These references fail to disclose or suggest doubling the

chromosome number of an unstable apomict to produce a stable apomict. Hence, a *prima facie* case of obviousness has not been established. Accordingly, withdrawal of this ground of rejection is respectfully requested.

Claims 1-2, 5, 8-9, 12, and 15-18 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Saran in view of Bashaw et al., Apomictic Grasses, in 2 Principles of Cultivar Development 40-82 (Fehr ed. 1987) (hereinafter, "Bashaw").

The teachings of Saran were reviewed above. Briefly, Saran discloses production of apomictic plants from apomictic parents. Saran further discloses the effects of different photoperiods on facultativeness of a facultatively apomictic tetraploid *Dichanthium intermedium* hybrid. Saran fails to disclose or suggest genetic instability of the apomixis trait from generation to generation and further fails to disclose or suggest a method of stabilizing such genetic instability.

Bashaw discloses that results of genetic investigations of hybrids between sexual and apomictic plants indicate simple inheritance of apomixis. Bashaw at 45. Bashaw fails to disclose or suggest a method for stabilizing genetic instability of the apomixis trait.

The combination of Saran and Bashaw fails to disclose or suggest a method for genetically stabilizing genetic instability of

apomixis. This combination also fails to disclose or suggest doubling the chromosome number of an unstable apomict to result in a stable apomict. For these reasons, a *prima facie* case of obviousness has not been established with respect to the claims at issue. Therefore, withdrawal of the rejection of these claims under 35 U.S.C. § 103(a) is respectfully requested.

It is respectfully submitted that no *prima facie* case of obviousness has been established concerning any claim presently under consideration. Therefore, withdrawal of these grounds of rejection under 35 U.S.C. § 103 is respectfully requested.

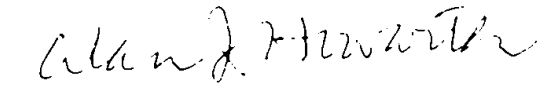
VII. Conclusion

Should the Examiner deem it advisable to conduct a telephone interview for any reason, the undersigned attorney would be most agreeable to receiving a telephone call to expedite the prosecution of the application.

For the reasons given above, Applicant respectfully requests reconsideration and allowance of Claims 1-2, 8-9, 15-17, and 19-24 and passage of this application to issue.

DATED this 29th day of July, 2003.

Respectfully submitted,



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